

REMARKS

The March 2, 2005 Office Action required restriction from among:

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| Group I | claim(s) 1-4, 11-23, 37 and 50-52, drawn to a polypeptide comprising SEQ ID NO: 2; |
| Group II | claim(s) 1, 2, 5-7, 11-23, 37 and 50-52, drawn to a polypeptide comprising SEQ ID NO: 4; |
| Group III | claim(s) 1, 3, 8-10, 11-23, 37 and 50-52, drawn to a polypeptide comprising SEQ ID NO: 6; |
| Group IV | claim(s) 24-26, 29-31, 37, 48, 50-52 and 60, drawn to a purified nucleic acid molecule encoding SEQ ID NO: 2; |
| Group V | claim(s) 24, 25, 27, 29-31, 37, 48, 58-52 and 60, drawn to a purified nucleic acid molecule encoding SEQ ID NO: 4; |
| Group VI | claim(s) 24, 25, 28, 29-31, 37, 48, 50-52 and 60, drawn to a purified nucleic acid molecule encoding SEQ ID NO: 6; |
| Group VII | claim(s) 32-33, 37, 50, 52 and 61, drawn to a ligand that specifically binds to SEQ ID NO: 2; |
| Group VIII | claim(s) 32-33, 37, 50, 52 and 61, drawn to a ligand that specifically binds to SEQ ID NO: 4; |
| Group IX | claim(s) 32-33, 37, 50, 52 and 61, drawn to a ligand that specifically binds to SEQ ID NO: 6; |
| Group X | claim(s) 34-36, 37, 50 and 52, drawn to a compound that either increases or decreases the level of expression or the activity of SEQ ID NO: 2; |
| Group XI | claim(s) 34-36, 37, 50 and 52, drawn to a compound that either increases or decreases the level of expression or the activity of SEQ ID NO: 4; |
| Group XII | claim(s) 34-36, 37, 50 and 52, drawn to a compound that either increases or decreases the level of expression or the activity of SEQ ID NO: 6; |
| Group XIII | claim(s) 38-40, 46 and 56, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising binding a ligand to the polypeptide; |
| Group XIV | claim(s) 38-40, 46 and 56, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 4, or assessing the activity of a polypeptide comprising SEQ ID NO: 4, relative to a control, the method comprising binding a ligand to the polypeptide; |
| Group XV | claim(s) 38-40, 46 and 56, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 6, or assessing the activity of a polypeptide comprising SEQ ID |

- NO: 6, relative to a control, the method comprising binding a ligand to the polypeptide;
- Group XVI claim(s) 41-42, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising binding a nucleic acid probe or primer to the gene encoding SEQ ID NO: 2;
- Group XVII claim(s) 41-42, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 4, or assessing the activity of a polypeptide comprising SEQ ID NO: 4, relative to a control, the method comprising binding a nucleic acid probe or primer to the gene encoding SEQ ID NO: 4;
- Group XVIII claim(s) 41-42, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 6, or assessing the activity of a polypeptide comprising SEQ ID NO: 6, relative to a control, the method comprising binding a nucleic acid probe or primer to the gene encoding SEQ ID NO: 6;
- Group XIX claim(s) 43-45, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising detecting the presence of a mutation in the gene encoding SEQ ID NO: 2;
- Group XX claim(s) 43-45, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising detecting the presence of a mutation in the gene encoding SEQ ID NO: 2;
- Group XXI claim(s) 43-45, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising detecting the presence of a mutation in the gene encoding SEQ ID NO: 2;
- Group XXII claim(s) 47 and 49, drawn to a method of using SEQ ID NO: 2 as an adhesion molecule;
- Group XXIII claim(s) 47 and 49, drawn to a method of using SEQ ID NO: 4 as an adhesion molecule;
- Group XXIV claim(s) 47 and 49, drawn to a method of using SEQ ID NO: 6 as an adhesion molecule;
- Group XXV claim(s) 53-55, drawn to a method of treating disease, comprising administering a polypeptide comprising SEQ ID NO: 2, or a pharmaceutical composition thereof;

- Group XXVI claim(s) 53-55, drawn to a method of treating disease, comprising administering a polypeptide comprising SEQ ID NO: 4, or a pharmaceutical composition thereof;
- Group XXVII claim(s) 53-55, drawn to a method of treating disease, comprising a polypeptide comprising SEQ ID NO: 6, or a pharmaceutical composition thereof;
- Group XXVIII claim(s) 53-55, drawn to a method of treating a disease, comprising administering a nucleic acid molecule that encodes SEQ ID NO: 2, or a pharmaceutical composition thereof;
- Group XXIX claim(s) 53-55, drawn to a method of treating a disease, comprising administering a nucleic acid molecule that encodes SEQ ID NO: 4, or a pharmaceutical composition thereof;
- Group XXX claim(s) 53-55, drawn to a method of treating a disease, comprising administering a nucleic acid molecule that encodes SEQ ID NO: 6, or a pharmaceutical composition thereof.
- Group XXXI claim(s) 53-55, drawn to a method of treating a disease, comprising administering a ligand that specifically binds to SEQ ID NO: 2, or a pharmaceutical composition thereof;
- Group XXXII claim(s) 53-55, drawn to a method of treating a disease, comprising administering a ligand that specifically binds to SEQ ID NO: 4, or a pharmaceutical composition thereof;
- Group XXXIII claim(s) 53-55, drawn to a method of treating a disease, comprising administering a ligand that specifically binds to SEQ ID NO: 6, or a pharmaceutical composition thereof;
- Group XXXIV claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to SEQ ID NO: 2;
- Group XXXV claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to SEQ ID NO: 4;
- Group XXXVI claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to SEQ ID NO: 6;
- Group XXXVII claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to a nucleic acid molecule encoding SEQ ID NO: 2;
- Group XXXVIII claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to a nucleic acid molecule encoding SEQ ID NO: 4;

- Group XXXIX claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to a nucleic acid molecule encoding SEQ ID NO: 6;
- Group XL claim(s) 58-59, drawn to a kit comprising a first container comprising a nucleic acid probe that hybridizes to a gene encoding SEQ ID NO: 2 and a second container comprising a primer for amplifying a gene that encodes SEQ ID NO: 2;
- Group XLI claim(s) 58-59, drawn to a kit comprising a first container comprising a nucleic acid probe that hybridizes to a gene encoding SEQ ID NO: 4 and a second container comprising a primer for amplifying a gene that encodes SEQ ID NO: 4;
- Group XLII claim(s) 58-59, drawn to a kit comprising a first container comprising a nucleic acid probe that hybridizes to a gene encoding SEQ ID NO: 6 and a second container comprising a primer for amplifying a gene that encodes SEQ ID NO: 6;
- Group XLIII claim(s) 62, drawn to a transgenic or knock-out animal that expresses a higher, a lower or no level of SEQ ID NO: 2;
- Group XLIV claim(s) 62, drawn to a transgenic or knock-out animal that expresses a higher, a lower or no level of SEQ ID NO: 4;
- Group XLV claim(s) 62, drawn to a transgenic or knock-out animal that expresses a higher, a lower or no level of SEQ ID NO: 6;
- Group XLVI claim(s) 63, drawn to a method of screening for a compound to treat disease, comprising contacting a transgenic animal that expresses a higher, a lower or no level of SEQ ID NO: 2 with a candidate compound;
- Group XLVII claim(s) 63, drawn to a method of screening for a compound to treat disease, comprising contacting a transgenic animal that expresses a higher, a lower or no level of SEQ ID NO: 4 with a candidate compound; and,
- Group XLVIII claim(s) 63, drawn to a method of screening for a compound to treat disease, comprising contacting a transgenic animal that expresses a higher, a lower or no level of SEQ ID NO: 6 with a candidate compound.

Furthermore, the Office Action additionally required an election of species from each of the following:

- a) each of the compounds listed in claim 36;
- b) each of the diseases listed in claim 46;
- c) each of the diseases listed in claim 52;

- d) each of the abnormal expression levels listed in claim 62 - higher or lower or absent; and,
- e) each of the abnormal expression levels listed in claim 63 - higher or lower or absent.

Applicants hereby elect, with traverse, the claims of Group III and inflammatory diseases. Applicants note that only one species has been elected herein in accordance with species (c) set forth in the Office Action on page 14 as the Group elected herein does not contain those claims referred to in the remaining species. Should the Examiner modify or withdrawn the restriction requirement, Applicants invite the Examiner to telephone the undersigned in order to obtain any additional required election of species.

The MPEP lists two criteria for a proper restriction requirement. First, the invention must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application “ [i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions.” *Id.*

The Office Action states that “searching each polypeptide or polynucleotide sequence imposes a serious search burden” as “there are approximately eight different databases that accompany the results of a search for one discrete amino acid sequence or nucleotide sequence” such that “the search for even two different polypeptides or nucleotides ... would require extensive searching and review.” Office Action at 7. Such a contention, however, is contrary to the decision of the Commissioner to “*sua sponte*” “partially waive the requirements of 37 C.F.R. 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application.” MPEP 803.04. Indeed, “[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes.” *Id.* Consequently, the present Office Action’s insistence that each of SEQ ID NOs: 2, 4, and 6 constitute a distinct and separate invention which must be searched separately appears incorrect. And, the Examiner is respectfully reminded that any burden placed on the Examiner by the search and examination of

more than a single sequence would be far less than the prejudice and burden placed on the Applicant should restriction be maintained such that the Applicant must file and prosecute over 45 separate applications in order to protect their invention. Accordingly, Applicants respectfully request that the claims be rejoined on the basis of the sequence claimed therein, such that Groups I, II and III be rejoined, allowing for the search and examination of claims 1-23, 37 and 50-52 as they relate to all of SEQ ID NOs: 2, 4 and 6.

Alternatively, at a minimum, it is respectfully asserted that the claims of Groups XXIV and XXVII should be rejoined with the claims of Group III. The claims of Group III are directed towards a polypeptide comprising SEQ ID NO: 6. The claims of Groups XXIV and XXVII are drawn to a method of using SEQ ID NO: 6 as an adhesion molecule, and to a method of treating disease, comprising administering a polypeptide comprising SEQ ID NO :6, or a pharmaceutical composition thereof, respectively. Such a rejoinder would not require the search of any sequence other than SEQ ID NO: 6, and the search of the claims for each Group would likely be co-extensive.

Group III includes claim 1, which relates to a polypeptide which (i) has the amino acid sequence as recited in SEQ ID NO:2, SEQ ID NO:4, or SEQ ID NO:6; (ii) is a fragment thereof having activity as an adhesion molecule or having an antigenic determinant in common with the polypeptide of (i); or (iii) is a functional equivalent of (i) or (ii). Accordingly, claim 1 already considers that “fragments” of SEQ ID NO: 6 have activity as an adhesion molecule. Therefore, claim 1 and the claims of Group XXIV are interrelated. Similarly, the claims of Group XXVII are interrelated to the vaccine and pharmaceutical compositions of the claims of Group III.

Accordingly, the claims as originally filed represent a web of knowledge and continuity of effort that merits examination as a single invention, at the very least such that the claims of Groups III, XXIV and XXVII are searched and examined together. Indeed, as the Office Action makes no showing that the Application meets the requirements for restriction the restriction requirement is improper and must be withdrawn, or at the very least, amended such that at a minimum, the claims of Groups III, XXIV, and XXVII (claims 1, 3, 8-10, 11-23, 37, 47, 49, 50-52 and 53-55) are searched and examined together.

M.P.E.P. § 808.01(a), states that “where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention” is required. In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

It is respectfully submitted that there is a disclosed relationship between the species as the species from which restriction was required include: (i) compounds which serve the same function in modulating the level of expression or activity of the polypeptide of claim 1; (ii) diseases related to the level of expression or activity of the polypeptide of claim 1; and (iii) abnormal expression levels which in any instance signify a change in the expression or activity of the polypeptide of claim 1. Furthermore, the species enumerated in the Office Action are sufficiently few in number that search and examination of the entire species would not place an undue burden on the Examiner. Therefore, reconsideration and withdrawal of the election of species requirement are requested.

In view of the remarks herein, enforcing the present restriction and election of species requirements would result in inefficiencies and unnecessary expenditures by the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially in view of the assertions in the Office Action as to the requisite showing of serious burden which are contrary to MPEP 803.04. Indeed, the search and examination of each Group would likely be co-extensive and, in any event, would involve such interrelated art that search and examination of the entire application can be made without undue burden on the Examiner. All of the preceding, therefore, mitigate against restriction and election species.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal, or at least modification, of the election of species and restriction requirements, such that, at the least, the claims of Groups XXIV and XXVII are searched and examined with the claims of Group III, or alternatively, the claims of Groups I, II and III are searched and examined together.

CONCLUSION

Reconsideration and withdrawal of the restriction requirement and election of species and an early and favorable examination on the merits is respectfully requested in view of the remarks herein.

Respectfully submitted,

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By:

A handwritten signature in black ink, appearing to read "Thomas J. Kowalski", is written over a horizontal line.

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